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PATENT SPECIFICATION

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(19)



(54) DENTIFRICES

(71) We, COLGATE-PALMOLIVE COMPANY, a Corporation organised under the Laws of the State of Delaware, United States of America, of 300 Park Avenue, New York, New York 10022, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:-

This invention relates to dentifrices which term is intended to include mouthwashes and mouth rinses as well as toothpastes, tooth powders and other preparations used for oral hygiene and prophylaxis.

Taste or flavour is perhaps the most important factor influencing consumer acceptance of a dentifrice. The selection and blending of ingredients with this factor in mind is therefore important in the formulation of a dentifrice, so that the final composition has a pleasing taste and is one in which the various selected ingredients are stable and provide their intended characteristics. Taste has presented particular difficulties, especially the taste associated with the surfactant that is almost always an essential ingredient in a commercially acceptable product. Therefore the formulator must have regard to the taste imparted to the product by the surfactant in selecting other ingredients.

Generally speaking, commercially available surfactants suitable for use in dentifrices have a bitter taste. This necessitates the inclusion of a sweetener to mask the bitterness. The inclusion of a sweetener further complicates matters in that this should be non-cariogenic, exhibit sufficient sweetness at low concentrations and be compatible with all the ingredients.

At the present time, there are a relatively few sweeteners which are both commercially available and generally acceptable for use in a dentifrice. One of the better known sweeteners is saccharin; however, its use may present some difficulties and often, when used as the sole sweetener, it too leaves a bitter taste. Some other available sweeteners are generally not acceptable for use in the dentifrice as they give rise to stability problems in relation to other ingredients of the dentifrice. Some of those sweeteners which do not present stability problems have the drawback that they are not suitable for use as a primary sweetener due to the unacceptable timelag prior to the onset of their sweetness and/or their associated side tastes. The sweetener employed must have the quality of a rapid onset of sweetness so as to mask the bitter flavour of the surfactant. Low intensity sweeteners, therefore, are not practical for use in most dentifrices. Merely increasing the proportion of low intensity sweetener in an attempt to overcome the foregoing deficiencies may not be practicable inasmuch as a dentifrice generally must contain large proportions of humectants, polishing agents, water and other ingredients which cannot be reduced to allow for increasing the proportion of sweetener.

A further consideration in formulating a dentifrice is that the dental polishing agents employed are generally adsorbent materials and therefore there may be a selective adsorption onto the polishing agent of the sweetener with accompanying change in physical form (in the case of a toothpaste), chemical changes and changes in resultant overall flavour.

This invention is directed to alleviating the problems referred to above.

According to the invention a dentifrice contains a surfactant having the formula, $R(OCH_2CH_2)_xOCH_2COOM$ wherein R represents a C_{8-18} alkyl chain, x represents an integer from 1 to 9 inclusive and M represents a nontoxic alkali metal or alkaline earth metal, ammonium or C_2 or C_3 alkylol amine, and a dental polishing agent when the dentifrice is in the form of a powder or paste, and an aqueous alcoholic medium when the

dentifrice is in the form of a liquid.

The said surfactant is efficacious in a dentifrice, is compatible with all usual dentifrice ingredients, does not exhibit a bitter taste and, if desired, allows one to formulate a dentifrice without the sweetener ordinarily needed to mask the surfactant taste. Alternatively, one may employ a smaller proportion of sweetener agent to provide the equivalent sweetening effect because its function of masking the taste of the surfactant has been removed.

A surfactant of the above formula may be called an alkyl polyglycol ether carboxylate. It may be derived from natural fatty alcohols having straight chains or from synthetic alcohols having straight or branched chains. The chain length of R in the formula is preferably from 10 to 16, more preferably 12 to 14 carbon atoms, x in the formula is preferably from 2 to 5 inclusive, most preferably 2, 3 or 4. The salt-forming ion represented by M in the formula may be any of the non-toxic alkali metal or alkaline earth metals, e.g. sodium, potassium or calcium. Also operative are the ammonium salts and C₂ or C₃ alkylol amines such as monoethanolamine, diethanolamine, triethanolamine and isopropanolamine salts.

The surfactant may be synthesized as is disclosed by Dr J. G. Aalbers in "Lauryl (Poly-l-Oxapropne) Oxaethane Carboxylic Acids" published by Drukkeig Wed G. Van Soest N. W., Amsterdam, 1964.

The surfactant preferably may be employed in the dentifrice in amounts in the range from 0.05 to 5.0% by weight of the dentifrice.

The dentifrices of the invention may include liquids and solids that are proportioned to form a creamy mass of a consistency extrudable from an aerosol container or a collapsible tube (for example an aluminium or lead tube). In general, the liquids in a dental cream will comprise chiefly water, glycerine, aqueous solutions of sorbitol, propylene glycol or polyethylene glycol 440, including suitable mixtures thereof. It is advantageous usually to use a mixture of water and a humectant or binder such as glycerine or sorbitol or both. The total liquid content will generally be in range from 20 to 75% by weight of the dentifrice. It is preferred to use also a gelling agent in dental creams and gels, such as natural or synthetic gums or gum-like materials, for example, Irish moss, gum tragacanth, hydroxethyl cellulose, methyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, hydrophilic colloidal carboxyvinyl polymers such as those sold as "Carbopol 934" and "Carbopol 940" (CARBOPOL is a Trade Mark) and synthetic silicated clays such as those sold as "Laponite CP" and "Laponite SP" (LAPONITE is a trade mark). These grades of "Laponite" have the formula $[Si_8Mg_{5.1}Li_{10.6}H_{7.6}O_{24}]0.6+0.6$. The solid portion of a toothpaste or dental cream or gel is usually present in an amount of up to 10%, preferably 0.2 to 5%, by weight of the dentifrice.

In the preparation of tooth powders, it is usually sufficient to admix mechanically, e.g. by milling, the various solid ingredients, in appropriate quantities and particle sizes.

In chewable dental tablets the solids and liquids are proportioned similarly to the amounts in dental creams and the surfactant is blended with the solids and liquids. A waxy matrix such as polyethylene glycol having a molecular weight of about 6,000 may also be employed in amounts in the range from 4 to 20% by weight in order to facilitate forming a tablet of desired size and shape.

In liquid dentifrices, such as mouthwashes, the aqueous alcoholic medium may be present in an amount in the range from 20 to 99% by weight of the dentifrice. Typically, the liquid medium includes from 5 to 30% by weight of the dentifrice of ethanol. Preferred mouthwashes generally will comprise approximately, by weight, (a) 64 to 85% water, (b) 5 to 25% ethanol and (c) 0.5 to 3% surfactant; more preferably 68 - 78% water and up to 15% of at least one material selected from the glycerine, sorbitol and propylene glycol. Optimally, there will be present 10 to 20% ethanol, 8 to 12% glycerine and 0.01 to 2% of sweetener and/or flavour.

Where desired, the said surfactant may be used together with one or more other surfactants commonly used in dentifrices. In that case the relative amounts of the surfactants will be adjusted so as to achieve the desired result, maintaining the total surfactant content within the limits aforementioned. Generally speaking, proportions of 1:99 to 99:1, one relative to the other, are satisfactory, preferably 1:5 to 5:1.

Other surfactants that may be employed in the dentifrice together with the surfactant of the above formula may be anionic, nonionic or ampholytic in nature, and it is preferred to employ a detergent material which imparts to the dentifrice detergent and foaming properties. Suitable such detergents are water-soluble organic salts, such as sulphates, having long chain (at least C₈) alkyl radicals; for instance water-soluble higher fatty acid monoglyceride monosulphates, such as the sodium salt of the monosulphated monoglyceride of hydrogenated coconut oil fatty acids; higher alkyl sulphate, such as sodium lauryl sulphate; alkyl aryl sulphonates, such as sodium dodecyl benzene sulphonate; higher alkyl sulphaacetates; higher fatty acid esters of 1,2-dihydroxy propane sulphonates; olefin sulphonates and substantially saturated higher aliphatic acyl amides of aliphatic amino carboxylic acid com-

pounds, having from 12 to 16 carbon atoms in the high alkyl, higher fatty acid, or higher aliphatic acyl radicals. Examples of the last mentioned amides are N-lauroyl sarcosine, and the sodium, potassium and ethanolamine salts of N-lauroyl, N-myristoyl or N-palmitoyl sarcosine, which should be substantially free from soap or similar higher fatty acid material which tends substantially to reduce the effect of these compounds. The use of these sarcosinate compounds in dentifrices is particularly advantageous since these materials exhibit a prolonged and marked effect in the inhibition of acid formation in the oral cavity due to carbohydrate breakdown in addition to exerting some reduction in the solubility of tooth enamel in acid solutions.

Other particularly suitable surfactants include nonionic agents such as condensates of sorbitan mono-stearate with approximately 60 moles of ethylene oxide, condensates of ethylene oxide with propylene oxide, condensates of propylene glycol ("Pluronic" - PLURONIC is a trade mark) and amphoteric agents such as quaternized imidazole derivatives which are available under the trade mark MIRANOL such as "Miranol C₂M". Other suitable nonionic detergents are the condensation products of an α -olefin oxide containing 10 to 20 carbon atoms, a polyhydric alcohol containing 2 to 10 carbons and 2 to 6 hydroxyl groups, and either ethylene oxide or a heteric mixture of ethylene oxide and propylene oxide. The resultant detergents are heteric polymers having a molecular weight in the range from 400 to 1,600 and containing 40% to 80% by weight of ethylene oxide, with an α -olefin oxide to polyhydric alcohol mole ratio in the range from 1:1 to 1:3. These detergents may be manufactured using well known polymerization techniques under conditions of high temperature and high pressure. The olefin oxide and polyhydric alcohol usually are added to the reactor prior to the addition of ethylene oxide. These nonionic detergents may be mixed with similar nonionic detergents as well as surfactants of other types such as anionic phosphate surfactants in which the anionic solubilizing group attached to the hydrophobic group is an oxyacid of phosphorus. Suitable anionic phosphate surfactants are the sodium, potassium and ammonium alkyl phosphate esters, such as those of the formulae $(R-O)_2PO_2M$ and $R-OPO_3M_2$ in which R represents an alkyl chain containing 8 to 20 carbon atoms or an alkyl phenyl group having 8 to 20 atoms and M represents a soluble cation. The compounds formed by including from 1 to 40 moles of ethylene oxide in the foregoing esters, e.g. compounds of the formula $[R-O(EtO)_n]_2PO_2M$ where n is a number from 1 to 40, are also satisfactory.

Dental cream formulations will generally also include a dentally acceptable, substantially water-insoluble, polishing agent of the type commonly employed in dental creams. Representative polishing agents are for example, dicalcium phosphate dihydrate and anhydrous tricalcium phosphate, insoluble sodium metaphosphate, aluminium hydroxide, including hydrated alumina, colloidal silica, magnesium carbonate, calcium carbonate, calcium pyrophosphate, bentonite and suitable mixtures thereof. Preferred polishing agents are the water-insoluble phosphates, more particularly insoluble sodium metaphosphate and/or a calcium phosphate such as dicalcium phosphate dihydrate. For toothpastes which are visually clear gels, a polishing agent of colloidal silica, such as those sold under the trade mark SYLOID, e.g. "Syloid 72" and "Syloid 74", or under the trade mark SANTOCEL, e.g. "Santocel 100", and synthetic alkali metal aluminosilicate complexes, may be particularly useful since they have refractive indices close to the refractive indices of gelling agent-liquid systems (generally including humectants such as glycerine and sorbitol) commonly used in dentifrices. When a polishing agent is employed the content thereof is generally in the range from 15 to 75% by weight in a dental cream. In a visually clear gel the total content of polishing agent is generally in the range from 5 to 50% by weight.

Various other adjuvant materials may be incorporated in the dentifrices of this invention. Examples are colouring or whitening agents or dyestuffs, preservatives, silicones, chlorophyll compounds, ammoniated materials such as urea or diammonium phosphate, and mixtures thereof. These adjuvants may be incorporated in the dentifrices in suitable amounts which do not substantially adversely effect the properties and characteristics desired.

The dentifrices of the present invention may also contain a fluorine compound having a beneficial effect on the care and hygiene of the oral cavity, e.g. diminution of enamel solubility in acid and protection of the teeth against decay. Examples are sodium fluoride, stannous fluoride, potassium fluoride, potassium stannous fluoride ($SnF_2 \cdot KF$), sodium fluorozirconate, potassium fluorozirconate, sodium hexafluorostannate, stannous chlorofluoride, sodium monofluorophosphate and mixtures thereof. These materials, which dissociate or release fluorine-containing ions, may be present in an effective but non-toxic amount, usually in the range from 0.1 to 1% by weight calculated as the water-soluble fluorine content thereof. Sodium fluoride, stannous fluoride, sodium monofluorophosphate and mixtures thereof are particularly preferred, as well as mixtures thereof.

Antibacterial agents may also be employed in the dentifrices of the invention, e.g. to

provide a total content of such agents of up to 5% by weight, preferably from 0.01 to 5.0% and most preferably from 0.05 to 1.0%. Typical antibacterial agents are:

- N¹-(4-chlorobenzyl)-N⁵-(2,4-dichlorobenzyl) biguanide;
 5 *p*-chlorophenyl biguanide;
 4-chlorobenzhydryl biguanide;
 4-chlorobenzhydrylguanilyurea;
 N-3-lauroxypropyl-N⁵-*p*-chlorobenzylbiguanide;
 1-(lauryldimethylammonium)-8-(*p*-chlorobenzyl-dimethylammonium) octane dichloride;
 5,6-dichloro-2-guanidinobenzimidazole;
 10 N¹-*p*-chlorophenyl-N⁵-laurylbiguanide;
 1,6-di-*p*-chlorophenyl biguanido-hexane;
 1,6-bis(2-ethylhexyl biguanido) hexane;
 5-amino-1,3-bis(2-ethylhexyl)-5-methylhexahydropyrimidine;
 and their non-toxic acid addition salts.
 15 Synthetic finely divided pyrogenic silicas such as those sold under the trade marks CABOSIL, SYLOID and AEROSIL, e.g. "Cab-O-Sil M-5", "Syloid 244", "Syloid 266" and "Aerosil D-200" may also be employed in amounts in the range from 1 to 5% by weight to promote thickening or gelling and to improve clarity of the dentifrice.
 20 The taste of dentifrices may be modified by employing suitable flavouring or sweetening materials. Examples of suitable flavouring materials are flavouring oils, e.g. oils of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon and orange, and sodium methylsalicylate. Suitable sweetening materials include sucrose, lactose, maltose, saccharine, sorbitol and perillartine. Suitably, flavour and sweetening materials may together constitute from 0.01 to 5% or more of the dentifrice.
 25 The dentifrices can also be provided with the distinctive biting flavour of chloroform. Accordingly, instead of or in addition to the foregoing flavouring and/or sweetening materials, a dentifrice can include up to 5%, preferably 0.1 and 5%, by weight of chloroform or chloroform flavouring.
 30 It is desirable that the pH of the dental cream formulations be in the range from 3 to 10, which may be accomplished where necessary by employing acids such as citric, acetic, chloropropionic, malonic, formic, fumaric, methoxyacetic and propionic or salts thereof. Lower pH's than 3 are generally undesirable for oral use. When stannous ions are present, the pH is preferably lower than 5. The preferred pH range is from 3.5 to 5.0 when stannous ions are present and from 4.5 to 7.0 in the absence of stannous ions.
 35 The following Examples illustrate the invention. Dental cream formulations are prepared in the conventional manner, except as indicated. All amounts and proportions are by weight except as otherwise indicated.

EXAMPLE 1 - DENTAL CREAM

		%	
40	Glycerine	9.474	40
45	Sorbitol	17.000	
	Sodium carboxymethylcellulose	1.100	45
	Sodium benzoate	0.500	
50	C ₁₂ (OCH ₂ CH ₂) ₂ -OCH ₂ COONa (surfactant)	2.000	50
	Sodium saccharin	0.200	
	Sodium monofluorophosphate	0.760	
55	Titanium dioxide	0.400	55
	Insoluble sodium metaphosphate	41.850	
	Anhydrous dicalcium phosphate	5.000	
60	Alumina - hydrated	1.000	60
	Flavour	1.000	
	Water	to 100	
65		100.000	65

EXAMPLE 2 - DENTAL CREAM

		<u>PARTS</u>	
5	Antimicrobial agent	0.1	5
	Sodium benzoate	0.15	
10	$C_{14}(OCH_2CH_2)_3-OCH_2COOK$ (surfactant)	2.00	10
	Sodium saccharine	0.2	
	Insoluble sodium metaphosphate	40.6	15
15	Dicalcium phosphate dihydrate	5.0	
	Titanium dioxide	0.4	
20	Stannous fluoride	1.4	20
	Gum tragacanth	1.0	
	Oil of wintergreen	1.0	25
25	Colour	0.03	
	Glycerine (99.3%)	27.10	
30	Water	to 100	30
		100.00	

This composition is used by brushing the teeth therewith at least once daily.
In the above dental cream, sodium lauryl sulphate or sodium-N-lauroyl sarcosinate may be employed in place of part of the specified surfactant.

EXAMPLE 3 - DENTAL CREAM

		<u>PARTS</u>	
45	Antimicrobial agent	0.1	45
	Sodium benzoate	0.5	
50	Tetrasodium pyrophosphate	0.25	50
	Dicalcium phosphate dihydrate	36.75	
	Calcium carbonate	5.0	
55	Sodium carboxymethylcellulose	0.75	55
	$C_{16}(OCH_2CH_2)_5OCH_2COOCa$ (surfactant)	2.00	
60	Glycerine (99.3%)	23.95	60
	Oils of peppermint and spearmint, 1:1	0.8	
65	Water	to 100	65

**EXAMPLE 4
TRANSPARENT DENTAL CREAM**

		<u>PARTS</u>	
5	Glycerine	25.00	5
	Sodium carboxymethylcellulose	0.70	
10	$C_{16}(OCH_2CH_2)_5OCH_2COONa$ (surfactant)	2.0	10
	Sorbitol (70%)	44.83	
15	Sodium aluminium silicate	16.00	15
	"Syloid 244"	5.00	
20	Flavour	1.00	20
	Sodium lauryl sulphate	2.00	
25	Water	to 100	25

**EXAMPLE 5
CHLOROFORM-CONTAINING
DENTAL CREAM**

	<u>COMPONENTS</u>	<u>PARTS</u>	
35	Glycerine	22.00	35
40	Sodium carboxymethylcellulose	0.80	40
	Tetrasodium pyrophosphate	0.25	
45	Sodium benzoate	0.50	45
	$C_{12}(OCH_2CH_2)_4OCH_2COONa$ (surfactant)	2.0	
50	Water	20.95	50
	Dicalcium phosphate dihydrate	46.00	
	Calcium carbonate	5.50	
55	Flavour oil	1.00	55
	Chloroform	1.00	
60		100.00	60

EXAMPLE 6 CLEAR DENTAL CREAM

The following visually clear dental cream
is prepared:

<u>COMPONENTS</u>	<u>PARTS</u>	
Sorbitol (70%)	45.0	10
Glycerine	25.0	
"Laponite SP"	1.0	
$C_{10}(OCH_2CH_2)_1OCH_2COONa$ (surfactant)	2.0	15
"Aerosil D200"	5.0	
Sodium aluminumsilicate	16.0	20
Flavour	1.0	
Colour	1.0	25
Water	5.0	

The sodium aluminumsilicate employed is a complex having a refractive index of 1.46, a moisture content of about 6%, an average particle size of about 35 microns and a sieve loose bulk density of about 0.07 g/cc.

EXAMPLE 7 MOUTH RINSE

	<u>PARTS</u>	
Antimicrobial agent	0.1	45
$C_{12}(OCH_2CH_2)_4OCH_2COONa$ (surfactant)	0.6	
Saccharin	0.035	50
Alcohol	14.78	
Water	83.87	
Colour	0.04	55
Oil of lemon	0.50	

This composition is used by rinsing the oral cavity with about 10 cc thereof one or more often daily.

EXAMPLE 8 CHEWABLE TABLET FOR

		PARTS	
5	Insoluble sodium metaphosphate	32.59	5
	Dicalcium phosphate dihydrate	4.03	
10	Poly(ethylene glycol) having a molecular weight of about 6,000	5.00	10
	Sodium saccharine	0.25	
15	Sodium carboxymethylcellulose	1.25	15
	C ₁₅ (OCH ₂ CH ₂) ₈ OCH ₂ COONa surfactant)	2.25	
20	Starch	3.0	20
	Mannitol	47.3	
25	Talc	0.5	25
	Magnesium stearate	1.25	
	Flavour and colour	2.48	
30	Antimicrobial agent	0.1	30

35 This product is employed as a dentifrice by introducing into the mouth a tablet thereof having a weight of about 0.5 grams, crushing it between the teeth, and then brushing the teeth in the usual fashion with saliva acting as a fluid vehicle for the crushed tablet particles. 35

WHAT WE CLAIM IS:-

- 40 1. A dentifrice (as hereinbefore defined) containing a surfactant having the formula, R(OCH₂CH₂)_xOCH₂COOM wherein R represents a C₈₋₁₈ alkyl chain, x represents an integer from 1 to 9 inclusive and M represents a non-toxic alkali metal or alkaline earth metal, ammonium or C₂ or C₃ alkylol amine, and a dental polishing agent when the dentifrice is in the form of a powder or paste, and an aqueous alcoholic medium when the dentifrice is in the form of a liquid. 40
- 45 2. A dentifrice as claimed in Claim 1 wherein M represents potassium, calcium or sodium. 45
3. A dentifrice as claimed in Claim 1 or Claim 2 wherein x represents an integer from 2 to 5 inclusive.
- 50 4. A dentifrice as claimed in any of the preceding Claims wherein R represents a C₁₀₋₁₆ alkyl chain. 50
5. A dentifrice as claimed in any of the preceding Claims wherein the surfactant is present in an amount in the range from 0.05% to 5.0% by weight.
- 55 6. A dentifrice as claimed in any of the preceding Claims containing from 0.01 to 5% by weight of flavouring oil, sweetening agent or mixture thereof. 55
7. A dentifrice as claimed in any of the preceding Claims wherein the aqueous alcoholic medium contains from 5 to 30% by weight of the dentifrice of ethanol.
8. A dentifrice as claimed in any of Claims 1 to 6 in which the polishing agent is present in an amount in the range from 15 to 75% by weight.
- 60 9. A dentifrice as claimed in any of the preceding Claims containing a fluorine compound having a beneficial effect on the care and hygiene of the oral cavity. 60
10. A dentifrice as claimed in Claim 9 wherein the fluorine compound is selected from sodium fluoride, stannous fluoride, potassium fluoride, potassium stannous fluoride, sodium hexafluorostannate, stannous chlorofluoride, sodium fluorozirconate, potassium fluorozirconate, sodium monofluorophosphate and mixtures thereof. 65

11. A dentifrice as claimed in any of the preceding Claims containing an anti-bacterial agent.

12. A dentifrice as claimed in any of the preceding Claims containing also another surfactant.

5 13. A dentifrice as claimed in Claim 12 wherein the other surfactant is a water-soluble organic sulphate having a long chain (at least C₈) alkyl radical.

14. A dentifrice as claimed in Claim 15 wherein the other surfactant is an olefin sulpho-

10 15. A dentifrice as claimed in any of Claims 1 to 6 or 8 to 14 in the form of a visually clear toothpaste.

16. A dentifrice as claimed in any of Claims 1 to 6 or 8 to 14 in the form of a chewable tablet.

15 17. A dentifrice as claimed in any of Claims 1 to 7 or 9 to 14 in the form of a mouthwash containing, by weight (a) 64 to 85% water, (b) 5 to 25% ethanol and (c) 0.5 to 3% of the surfactant.

18. A mouthwash as claimed in Claim 17 containing, by weight, 68 to 78% water and up to 15% of at least one material selected from glycerine, sorbitol, propylene glycol and mixtures thereof and wherein the alcohol is ethanol.

20 19. A mouthwash as claimed in Claim 18 containing, by weight, 10 to 20% ethanol, 8 to 12% glycerine and 0.01 to 2% of sweetener and/or flavour.

20. A dentifrice substantially as described in any of the Examples.

21. A packaged dispensable product for dental hygiene comprising a container having therein a measured amount of a dentifrice as claimed in any of the preceding Claims.

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